

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DIOMED, INC.,

Plaintiff,

v.

VASCULAR SOLUTIONS, INC.,

Defendant.

MAGISTRATE JUDGE

Civil Action No.

04 10444 RGS

RECEIPT # 54289

AMOUNT \$150.00

SUMMONS ISSUED Y

LOCAL RULE 4.1

WAIVER FORM

MCF ISSUED

BY DPTY. CLK. Cuy 6

DATE 3-4-04

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Diomed, Inc. ("Plaintiff" or "Diomed"), for its complaint against

Defendant Vascular Solutions, Inc. ("Defendant" or "VSI"), alleges as follows:

THE PARTIES

1. Diomed is a Delaware corporation with a place of business at One Dundee Park, Suite 5/6, Andover, Massachusetts 01810.

2. VSI is a Minnesota corporation with a place of business at 6464 Sycamore Court, Minneapolis, Minnesota.

FACTUAL BACKGROUND

3. Diomed is a leading developer of technology for minimally invasive endovascular laser treatment, in particular for varicose veins.

4. It is estimated that between 25-40 million Americans suffer from venous insufficiency, which can lead to varicose veins. Diomed's laser treatment, sold under the

mark EVLT®, represents the next generation of minimally invasive treatment of varicose veins.

5. Prior to Diomed's introduction of its EVLT® system, procedures known as ligation/stripping and radio-frequency ablation were the only available treatment methods for most varicose vein abnormalities that originate from "reflux" of the greater saphenous vein.

6. Compared to surgical treatment methods, Diomed's EVLT® system provides the advantages of reduced pain and discomfort, no scarring, and a minimal recovery period. The procedure also takes less than 45 minutes, without the need for general anesthesia or hospitalization. Published clinical studies indicate that EVLT® has a 93.4% long-term success rate.

7. Diomed's EVLT® system includes a laser and a disposable procedure kit that contains a vascular access needle, guidewire, introducer, laser fiber, and a sheath which is used to guide the laser fiber to the targeted treatment area where the energy is delivered.

8. A practitioner is able to treat varicose veins with Diomed's EVLT® system by making one small incision or puncture and inserting the disposable EVLT® sheath into the vein. Once the sheath is in place, the practitioner inserts the laser fiber into the sheath. The laser is activated and energy is delivered from the fiber to the vein. The laser fiber and sheath are then slowly removed and the vein eventually closes. After being fitted with compression hose, the patient is able to walk out of the physician's office within an hour of treatment.

9. The EVLT® procedure causes minimal discomfort and bruising and no scarring, and, as noted above, requires less recovery time than the more invasive surgical methods which often require general or spinal anesthesia. Diomed's EVLT® procedure is thus a preferable alternative treatment method in terms of lower treatment costs and costs associated with extended absences from work.

10. Along with lasers and single-use procedure kits for EVLT®, Diomed provides its customers with state of the art physician training and support.

11. Since the commercial launch of the EVLT® system in January 2002, Diomed has established itself as the market leader of minimally invasive laser treatment solutions for varicose veins, and the EVLT® system has received high praise from the medical community, patients, and industry experts, as documented in clinical studies.

12. Diomed's EVLT® system has been successfully used in more than 10,000 procedures since the FDA granted clearance for the procedure in January 2002.

13. Diomed has made a substantial investment of time, capital and resources in developing its EVLT® technology. Diomed has spent over \$20 million commercializing EVLT® over the last three years.

14. VSI competes with Diomed in the market for minimally invasive endovascular laser treatments. As described in more detail below, VSI's activities constitute infringement of Diomed's U.S. Patent No. 6,398,777 ("the '777 patent"), which is directed to various aspects of Diomed's proprietary endovascular laser treatment technology.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, Title 35 of the United States Code.

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338.

17. This Court has personal jurisdiction over VSI, which on information and belief does business in this District, including the infringing activities recited below.

18. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391, 1400.

COUNT ONE

(Infringement of U.S. Patent No. 6,398,777).

19. Diomed repeats and re-alleges the allegations in the paragraphs above as if fully set forth herein.

20. Diomed is the owner of all right, title and interest in the '777 patent that formerly belonged to one inventor thereof, Robert J. Min. Diomed also has an exclusive license to the '777 patent, including the right to sue for infringement of the '777 patent (and all other substantial rights in the '777 patent), from the entity to which the remaining inventors thereof conveyed such rights. A copy of the '777 patent, including a certificate of correction issued by the United States Patent and Trademark Office on April 29, 2003, is attached hereto as Exhibit A.

21. VSI sells a kit for laser treatment of varicose veins under the name "Vari-Lase," and a laser for use therewith, under the name "Vari-Lase laser console" (collectively, the "VSI Product").

22. On information and belief, VSI instructs physicians in using the VSI Product (the "VSI Instructions").

23. VSI has infringed, and/or contributorily infringed, and/or induced infringement of, the '777 patent through one or more of the following activities: (a) making, using, offering to sell, and selling, the VSI Product; and/or (b) inducing others to use the VSI Product (through the VSI Instructions, by selling and/or offering to sell the VSI Product, and/or otherwise).

24. VSI continues to infringe, and/or contributorily infringe, and/or induce infringement of, the '777 patent through the aforementioned activities.

25. On information and belief, VSI's infringement of, contributory infringement of, and/or inducement to infringe the '777 patent have been, and continue to be, knowing and willful.

26. VSI's infringement of, contributory infringement of, and/or inducement to infringe the '777 patent have caused, and continue to cause, Diomed to suffer substantial damages.

27. VSI's infringement of, contributory infringement of, and/or inducement to infringe the '777 patent have caused, and unless enjoined by the Court will continue to cause, Diomed irreparable harm for which there is no adequate remedy at law.

RELIEF REQUESTED

WHEREFORE, Diomed requests that this Court:

- A. Enter judgment that VSI has infringed the '777 patent.
- B. Enter a preliminary and permanent injunction enjoining VSI and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees,

successors, assigns, and all those acting for it or on its behalf, or acting in concert or privity with it, from committing, inducing or contributing to infringement of the '777 patent;

- C. Award Diomed compensatory damages under 35 U.S.C. § 284;
- D. Award Diomed treble damages under 35 U.S.C. § 284.
- E. Award Diomed its reasonable attorney fees pursuant to 35 U.S.C. § 285 or other applicable law;
- F. Award Diomed its costs and interest pursuant to 35 U.S.C. § 284 or other applicable law; and
- G. Award Diomed such other relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Diomed hereby demands a jury trial on all issues so triable.

DIOMED, INC.,

By its attorneys,



Dated: March 4, 2004

Michael A. Albert (BBO #558566)

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Michael N. Rader (BBO #646990)

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